



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/648,976	01/03/2007	David E. Francischelli	P-8575.07	6648

28390 7590 01/26/2017
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

DELLA, JAYMI E

ART UNIT	PAPER NUMBER
----------	--------------

3739

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

01/26/2017

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com
medtronic_cv_docketing@cardinal-ip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID E. FRANCISCHELLI, SCOTT E. JAHNS, and
JAMES R. KEOGH

Appeal 2014-007866
Application 11/648,976¹
Technology Center 3700

Before STEFAN STAICOVICI, AMANDA F. WIEKER, and
SEAN P. O'HANLON, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

David E. Francischelli et al. (Appellants) appeal under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1–3, 5–7, 9, 11–17, 20–24, 34, 35, 37, 38, 40–45, 47–51, and 53–61.² We have jurisdiction over this appeal under 35 U.S.C. § 6(b).

¹ According to Appellants, the real party in interest is Medtronic, Inc. Br. 1 (filed Feb. 10, 2014).

² Claims 8, 10, 18, 19, 39, 46, and 52 are withdrawn and claims 4, 25–33, and 36 are canceled. *See* Appellants' Amendment 11 (filed Aug. 15, 2013).

SUMMARY OF DECISION

We REVERSE.

INVENTION

Appellants' invention "relates to ablation devices that are used to create lesions in tissue." Spec. 1.

Claims 1, 16, and 34 are independent. Claim 1 is illustrative of the claimed invention and reads as follows:

1. An ablation apparatus comprising:
 - a maneuvering mechanism;
 - a conductive element attached to the maneuvering mechanism;
 - a sensor attached to the maneuvering mechanism and operatively adapted to sense vibration including an initial vibration in organic tissue prior to an application of ablation energy and a self-generated simmering vibration emanating from the organic tissue in response to the application of ablation energy; and
 - an output device in communication with the sensor and operatively adapted to respond when a difference value has reached a given value, the difference value determined by comparison between a sensed initial signal from the sensor corresponding to the sensed initial vibration and a sensed second signal from the sensor corresponding to the sensed self-generated simmering vibration.

REJECTIONS

The following rejections are before us for review:

- I. The Examiner rejected claims 1–3, 5–7, 9, 11–17, 20–24, 34, 35, 37, 38, 40–45, 47–51, and 53–61 under 35 U.S.C. § 112,

first paragraph, as failing to comply with the written description requirement.

- II. The Examiner rejected claims 12, 13, and 38 under 35 U.S.C. § 112, second paragraph, as being indefinite.³
- III. The Examiner rejected claim 38 under 35 U.S.C. § 112, fourth paragraph, as failing to further limit the subject matter of the claim upon which it depends.
- IV. The Examiner rejected claims 1–3, 5–7, 9, 11, 15–17, 20–22, 24, 34, 41, 43, 47, 49, and 53–57 under 35 U.S.C. § 103(a) as being unpatentable over Nardella '281 (US 5,733,281, iss. Mar. 31, 1998) and Mizukawa (US 5,628,771, iss. May. 13, 1997).
- V. The Examiner rejected claims 13, 37, 38, and 40 under 35 U.S.C. § 103(a) as being unpatentable over Nardella '281, Mizukawa, and Nardella '193 (US 5,334,193, iss. Aug. 2, 1994)⁴.
- VI. The Examiner rejected claims 14, 23, 44, 45, 50, and 51 under 35 U.S.C. § 103(a) as being unpatentable over Nardella '281, Mizukawa, and Nardella '091 (US 5,817,091, iss. Oct. 6, 1998).

³ The rejection under 35 U.S.C. § 112, second paragraph, of claims 1–3, 5–7, 9, 11, 14–17, 20–24, 34, 35, 37, 40–45, 47–51, and 53–61 as being indefinite, is withdrawn by the Examiner. *See* Ans. 5 (transmitted May 8, 2014).

⁴ The rejection under 35 U.S.C. § 103(a) of claim 12 as being unpatentable over Nardella '281, Mizukawa, and Nardella '193, is withdrawn by the Examiner. *See id.* at 5–6.

- VII. The Examiner rejected claim 35 under 35 U.S.C. § 103(a) as being unpatentable over Nardella '281, Mizukawa, and Eggers (US 6,047,700, iss. Apr. 11, 2000).
- VIII. The Examiner rejected claims 42 and 48 under 35 U.S.C. § 103(a) as being unpatentable over Nardella '281, Mizukawa, and Larnard (US 5,720,775, iss. Feb. 24, 1998).
- IX. The Examiner rejected claims 58–61 under 35 U.S.C. § 103(a) as being unpatentable over Nardella '281, Mizukawa, and Brucker (US 5,462,521, iss. Oct. 31, 1995).

ANALYSIS

Rejection I

The Examiner finds that the claimed “difference value” that is “determined by comparison between a sensed initial signal . . . and a sensed second signal” of independent claims 1, 16, and 34 lacks support in Appellants’ original disclosure. *See* Final Act. 6–8 (transmitted Sept. 10, 2013). More specifically, the Examiner finds that Appellants’ original disclosure fails to support that “a difference value is determined between the initial sensed vibration and a later sensed vibration” and that “‘too intense’ is determined by comparing the claimed difference value to a given value.”

Ans. 8. The Examiner explains that

while the initial state of tissue vibration is used as “a gauge to compare” with a latter state of vibration during the procedure, the comparison could just be a comparison of inequalities (i.e., $\text{initial} < \text{latter}$ or $\text{initial} > \text{latter}$) that is used as monitoring feedback to the user that is not acted upon by the user or the

apparatus and “too intense” could be determined by the sensed tissue vibration during the procedure reaching a given value.
Id.

The purpose of the written description requirement in 35 U.S.C. § 112, first paragraph, is to “‘clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.’” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). “[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* Although we appreciate that Appellants’ Specification does not include the phrase “difference value” we note that claimed subject matter need not be described *in haec verba* in the Specification in order for the specification to satisfy the description requirement. *In re Smith*, 481 F.2d 910, 914 (CCPA 1973).

In this case, Appellants’ Specification describes using “the initial state of tissue vibration [that] is measured” “as a *gauge* to compare with the state of tissue vibration during the procedure” and “[i]f the tissue vibration [during the procedure] becomes to[o] intense, the energy supplied to ablation apparatus 20 is modified or adjusted.” Spec. 18, ll. 25–30 (emphasis added); *see also id.* at Fig. 7. If we take the Examiner’s position that Appellants’ Specification describes only a comparison between tissue vibration during an ablation procedure and a given (preset) value to determine whether the vibration is “too intense,” there would not be a need to measure the initial state of tissue vibration. *See* Final Act. 30. As the initial state of tissue vibration is lower than tissue vibration during an ablation procedure, a comparison between the two values would not result in any useful

information. Rather, a user may simply monitor the tissue vibration during the ablation procedure and compare it to a given (preset) value to determine whether the vibration is “too intense” without having to measure the initial state of tissue vibration.

However, as noted above, Appellants’ Specification explicitly describes using “[t]he initial state of tissue vibration . . . as a *gauge* to compare with the state of tissue vibration during the procedure.” Spec. 18, ll. 25–27 (emphasis added). Therefore, because an initial state of tissue vibration is measured, a person of ordinary skill in the art would readily understand then that such a *gauge* represents a “difference value” between the initial state of tissue vibration and the tissue vibration during an ablation, as claimed by claim 1. *See* Br. 6. We thus agree with Appellants that “whether or not the tissue vibration is too intense is based on the comparison” between the initial state of tissue vibration and the tissue vibration during the ablation procedure, that is, on their difference. *See* Appeal Br. 5.

Hence, for the foregoing reasons, we do not sustain the rejection of claims 1–3, 5–7, 9, 11–17, 20–24, 34, 35, 37, 38, 40–45, 47–51, and 53–61 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Rejection II

With respect to the rejection of claims 12 and 13, which depend from the ablation apparatus of claim 1, the Examiner finds that the limitation of a “fluid supply in communication with the apparatus” is indefinite because it

is not clear whether Appellants are “claiming the combination (fluid supply & apparatus) or the sub-combination (apparatus) and it is further unclear how the apparatus can comprise a fluid supply in communication with itself.” Final Act. 10.

As to the rejection of claim 38, the Examiner finds that “it is unclear if claim 38 is intending to positively recite ‘irrigation fluid’ in the claim or if claim 38 is just further defining the functional language of claim 37,” from which claim 38 depends, and which does not positively recite an “irrigation fluid,” but rather an “irrigation fluid conduit.” *Id.* at 13–14.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted).

Here, the term “comprising” in claims 12 and 13 connotes that the ablation apparatus of claim 1, from which claims 12 and 13 depend, has elements in addition to those specifically set forth in claim 1, such as a “fluid supply in fluid communication with the ablation apparatus.” *See* Br. 17. Therefore, we agree with Appellants that in claims 12 and 13 it is clear “that a fluid supply is part of the broadly claimed ‘ablation apparatus’ and is in fluid communication therewith.” Br. 8.

With regards to claim 38, we note that claim 37, from which claim 38 depends, includes the functional limitation “for providing an irrigation fluid” that describes the function of the positively recited “irrigation fluid conduit.” Br. 20. Hence, the limitation in claim 38 of “the irrigation fluid is an energy

conducting fluid” further limits the functional limitation of claim 37. In other words, claim 38 requires, *inter alia*, “an irrigation fluid conduit for providing an irrigation fluid” that “is an energy conducting fluid.”

In conclusion, for the foregoing reasons, we do not sustain the rejection of claims 12, 13, and 38 under 35 U.S.C. § 112, second paragraph, as being indefinite.

Rejection III

The Examiner finds that because claim 37 does not positively recite “an irrigation fluid,” the limitation in claim 38 of “the irrigation fluid is an energy conducting fluid” does not further limit claim 37. Final Act. 14–15.

We do not agree with the Examiner’s position because as discussed *supra*, claim 37, from which claim 38 depends, includes the functional limitation “for providing an irrigation fluid” that describes the function of the positively recited “irrigation fluid conduit.” As such, the limitation in claim 38 of “the irrigation fluid is an energy conducting fluid” further limits the functional limitation of claim 37. We thus agree with Appellants that “under claim 37, the irrigation fluid conduit can provide any irrigation fluid, but in claim 38, the irrigation fluid conduit must provide an irrigation fluid that is an energy conducting fluid.” Br. 9.

Accordingly, we do not sustain the rejection of claim 38 under 35 U.S.C. § 112, fourth paragraph, as failing to further limit the subject matter of the claim upon which it depends.

Rejection IV

The Examiner finds that either of transducer 20 or microphone 170 of Nardella '281 constitutes a sensor, as called for by each of independent claims 1, 16, and 34. *See* Final Act. 16. More specifically, the Examiner finds that the sensor in Nardella '281

is taken to be one or both [of] (1) acoustical detection element/ultrasonic transducer 20 . . . [that] senses simmering vibrations that are reflected partly by the tissue and the surrounding gas/steam present in the surgical site or (2) microphone 170 on catheter 12 that detects sound at the surgical site, such as levels of steam and biological changes, and converts the sound to electrical signals that are carried along conductor 172 to speaker 180, which in turn transforms the electrical signals generated by the microphone into audible signals, both of which are capable of sensing vibration prior to and during the application of ablation energy; Col. 4, ll. 46-51, Col. 8-9, ll. 30-15, Col. 9, ll. 32-43, Claim 3.

Id.

Appellants argue that “the transducer 20 of Nardella ['281] does not sense self-generated simmering vibrations” and furthermore “Nardella ['281] does not disclose or suggest that microphone 170 is adapted to sense an initial vibration.” Br. 10.

Nardella '281 discloses an electrosurgical feedback system including a pulse generator 150 that emits an electrical pulse along conductor 152 to transducer 20 that emits ultrasonic energy that is reflected “partly by the tissue and partly by any surrounding gas, e.g., steam, that is present at the surgical site.” Nardella '281, col. 8, ll. 38–45. Nardella '281 further discloses that the reflected energy is received by transducer 20, which then

produces an electrical signal representative of the intensity of the reflected ultrasonic energy. *Id.*, col. 8, ll. 45–48.

As such, transducer 20 of Nardella '281 does not sense “a self-generated simmering vibration emanating from the organic tissue,” as called for by each of independent claims 1, 16, and 34, but rather senses vibration emanating from both tissue and surrounding gas. In other words, because sensor 20 of Nardella '281 senses the ultrasonic energy that is reflected by both tissue and any surrounding gas, the resulting electrical signal produced by sensor 20 is a compound signal representative of the intensity of the reflected ultrasonic energy of both tissue and any surrounding gas. Accordingly, the system of Nardella '281 does not generate “a sensed second signal . . . corresponding to the sensed self-generated simmering vibration” that can then be compared to a “sensed initial signal,” because the single electrical signal of Nardella '281 is a compound signal. Therefore, we agree with Appellants that “transducer 20 of Nardella ['281] does not sense self-generated simmering vibrations.” Br. 10.

Nardella '281 further discloses a microphone 170 that detects sound at the surgical site and converts the sound to electrical signals that are carried to speaker 180, which transforms the electrical signal into audible signals. Nardella '281, col. 8, l. 61–col. 9, l. 1. However, although microphone 170 detects sound at the surgical site, this does not mean that it can also detect “an initial vibration in organic tissue,” as called for by each of independent claims 1, 16, and 34. Although we appreciate that sound is vibration, nonetheless, it does not mean that the sound at a surgical site necessarily is the same as the vibration in organic tissue. The Examiner does not set forth

adequate factual findings or technical reasoning that would lead a person skilled in the art to make such a finding and thus, requires speculation on the Examiner's part. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967). Hence, we agree with Appellants that "Nardella ['281] does not disclose or suggest that microphone 170 is adapted to sense an initial vibration [in organic tissue]," as called for by each of independent claims 1, 16, and 34. Br. 10.

The Examiner's use of the disclosure of Mizukawa does not remedy the deficiency of Nardella '281 as discussed *supra*. *See* Final Act. 17. Therefore, we do not sustain the rejection of claims 1, 16, and 34 under 35 U.S.C. § 103(a) as unpatentable over Nardella '281 and Mizukawa.

As Appellants rely on the arguments discussed above to argue the rejection of claims 2, 3, 5–7, 9, 11, 15, 17, 20–22, 24, 41, 43, 47, 49, and 53–57, for the same reasons, we also do not sustain the rejection of these claims over the combined teachings of Nardella '281 and Mizukawa. *See* Br. 11.

Rejections V–IX

The Examiner's use of the disclosures of Nardella '193, Nardella '091, Eggers, Larnard, and Brucker does not remedy the deficiency of Nardella '281 as discussed *supra*. *See* Final Act. 25–30. Therefore, for the same reasons as discussed above we also do not sustain Rejections V–IX.

SUMMARY

The Examiner's decision to reject claims 1–3, 5–7, 9, 11–17, 20–24, 34, 35, 37, 38, 40–45, 47–51, and 53–61 is reversed.

REVERSED